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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,847	02/25/2004	David C. Gan	03.47	2937

23487 7590 10/17/2007

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EXAMINER	
VENKAT, JYOTHSNA A	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,847	GAN ET AL.	
	Examiner	Art Unit	
	JYOTHSNA A. VENKAT Ph. D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/14/07 and 5/9/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of election filed on 8/7/07 and receipt is also acknowledged of IDS filed on 8/14/07 and 5/9/05. Claims 1-24 are pending in the application and the status of the application is as follows:

Election/Restrictions

Applicant's election without traverse of group I in the reply filed on 8/7/07 is acknowledged.

Claims 20-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/7/07.

Claims 1-19 are pending in the application and the status of the application is as follows:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is " *undue* ". See ***In re Wands, 858 F.2d 731, 737, 8***

USPQ 2d 1400, 1404 (Fed. Cir. 1998). The court set forth the eight factors to consider when assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman, 230 USPQ 546*, the court recited eight factors

These factors include, but are not limited to:

1*) The breadth of the claims,*

2) The nature of the invention,

3) The state of the prior art,

4) The level of one of ordinary skill,

5) The level of predictability in the art,

6) The amount of direction provided by the inventor,

7) The existence of working examples

8) The quantity of experimentation needed to male or use the invention based on the content of the disclosure.

(1 and 2) The breadth of the claims and the nature of the invention: The claims are drawn to:

1. A method for increasing the proliferation of dermal papilla cells in hair follicles which comprises applying to the cells a composition containing a follicle-stimulating effective amount of a creatine compound or

13. A method for stimulating hair growth in an individual suffering from hair loss, which comprises topically applying to the hair and/or scalp of the individual a follicle-stimulating effective amount of a creatine compound.

14. The method of claim 13 in which the hair loss is due to male pattern baldness.

15. The method of claim 13 in which the hair loss is due to aging.

16. The method of claim 13 in which the hair loss is due to chemotherapy or drug exposure.

(3 and 5) *The state of the prior art and the level of predictability in the art:* The art is unpredictable with respect to stimulating hair growth and preventing hair loss.

(6-7) *The amount of direction provided by the inventors and the existence of working examples*

Specification under paragraph 21admits that certain concentration is effective in growing dermal papilla cells. See below.

[0021] Results: Creatine was found to significantly increase DNA synthesis in papilla cells (see Tables 1&2). At 0.25mM, creatine induced a 36% increase in DNA synthesis. At 0.5mM, creatine induced a 25% increase in DNA synthesis. At 1mM, creatine induced a 6% increase in DNA synthesis. Oxaloacetate was also found to significantly increase DNA synthesis in papilla cells in a dose dependent manner. At 0.25mM, Oxaloacetate induced a 22% increase in DNA synthesis. At 0.5mM, Oxaloacetate induced a 33% increase in DNA synthesis. At 1mM, Oxaloacetate induced a 38% increase in DNA synthesis. Positive results have also been observed with equivalent concentrations of AMP(1493% increase at .25 mM, 1930% at 0.5 mM, 1449% at 1 mM) and ATP(1411% increase at .25 mM, 1201% at .5 mM).

See below with respect to example 2.

[0023] **Example 2**. This example illustrates the increase in hair growth observed in hair plugs exposed to creatine.

[0024] **Methods:** Hair plugs were obtained from East Wood Medical Hair Transplant Surgery (Garden City, NY). These hair plugs were equilibrated in hair plug media as described in the literature (DMEM, 10% FBS, 1% PS, 25mg insulin, 25 µg fungizone). These hair plugs were measured under the microscope one the first day of arrival and treated with creatine at 1mM (n=6 for control and creatine group respectively). These hair plugs were then kept in the incubator at 37°C in 5% CO_2. On day 3, 7, & 10, re-treatments were made as well as measurements.

[0025] **Results:** The hair plugs were found to grow at a constant rate. In the untreated group, there was an average growth of 0.48mm at day 3 compared to day 0. There was an average growth of 0.73mm at day 7, and an average growth of 0.82mm at day 10. Creatine was found to significantly increase the growth rate of these hair plugs compared to the untreated plugs. There was an average growth of 0.95mm at day 3, 1.32mm at day 7, and 1.43mm at day 10 (Refer to Table 3, 4, and 5). These increases were all statistically significant.

[0026] **Discussion:** Creatine was found to significantly increase hair growth in hair plugs. This increase was nearly two fold compared to the untreated plugs. We previously observed creatine increasing DNA synthesis in dermal papilla cells. As dermal papilla cells influence and modulate the growth of hair, we postulate that creatine may be increasing hair plug growth by increasing the activity of dermal papilla cells.

Thus specification teaches that dermal papilla cell influence the hair growth. The testing is in vitro and the creatine tested for growing hair was 1mM. With respect to increase in dermal papilla cells, there are no test results for 1mM concentration of creatine. Note that creatine at 1mM concentration increase the DNA synthesis of 6%. Therefore there is discrepancy between dermal papilla cells influence and method of growing hair since DNA synthesis is indication of cell proliferation. The compound tested with respect to hair growth was in vitro and the results are with respect to creatine and not its metabolite creatine phosphate or cyclocreatine. There is no in vivo data. There are no test results that hair growth was observed using creatine, when the hair loss is due to male pattern baldness or the hair loss is due to aging or the hair loss is due to

chemotherapy or drug exposure. There is no in vivo data with respect to method for stimulating hair growth in an individual suffering from hair loss using creatine at any concentration let alone to an individual suffering from hair loss due to aging or chemotherapy or drug exposure. There is no data with respect preventing hair loss

(8) The quantity of experimentation needed to make or use the invention bases on the content of the disclosure: the art is unpredictable with respect to hair growth. There is no correlation between in vitro and in vivo data and compound tested was at low concentration and the test results show that 1 mM of creatine did not show increase in DNA synthesis. There are no test results that showed the hair loss was prevented (emphasis added). The instant specification gives one skilled in the art no indication that the one could use any amount of creatine or any amount of creatine phosphate or any amount of cyclocreatine and increase dermal papilla cells and have a reasonable expectation of success. The instant specification gives one skilled in the art no indication that the one could use any amount of creatine or any amount of creatine phosphate or any amount of cyclocreatine and stimulate the hair growth or prevent hair loss. Therefore further testing would be necessary to use the claimed invention and the practice of the full scope of the invention would require undue experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JYOTHSNA A VENKAT Ph. D
Primary Examiner
Art Unit 1615

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